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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,315	08/19/2003	John Spiridigliozzi	760-100 CIP	3552

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HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER

PRONE, CHRISTOPHER D

ART UNIT	PAPER NUMBER
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3738

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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/643,315	Applicant(s) SPIRIDIGLIOZZI ET AL.	
	Examiner Christopher D. Prone	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
 4a) Of the above claim(s) 16, 18, 34, 36 and 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17, 19-33, 35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/07 has been entered.

Response to Arguments

Applicant's arguments filed 2/27/07 have been fully considered but they are not persuasive. The applicant argues that the pleats of Banas are wound but not pleated. The examiner believes that the layers of Banas are folded to form waves, which is the definition of a pleat. The process of making the pleats used by Banas may be different than that of the current application, but the final structures are the same. Both will allow for expansion upon deployment. Furthermore the applicant defines a process of making pleats by wrapping.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-15, 17, 19-33, 35, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The independents have been amended to require that the elastomeric bonding agent is applied "between said pleated folds", but there is no disclosure of this anywhere in the specification. The specification supports applying the agent to either the first or second layer, but fails to define the location. The disclosure also fails to support that the pleated folds are "not secured to said second layer."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 17, 19-33, 35, and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-17 of copending Application No. 10/166,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite all the same structural requirements.

In regards to claims 1-15 and 17, Independent claim 1 recites that the implant comprises a first tubular layer of ePTFE and a second tubular layer of a textile material, these layers correspond to the first and third layers of claim 1 in copending Application No. 10/166,842. This claim is broader than the claim of copending Application No. 10/166,842 but it still contains the same structural limitations.

In regards to claims 19-33, 35, and 37, these claims clearly recite all the same structural limitations as claims 1-3 and 5-17 of copending Application No. 10/166,842.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15, 17, 19-33, 35, and 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Planck (4,850,999) in view of Banas (USPN 6,264,684), and further in view of Pinchuk (USPN 5,628,788).

With reference Figure 1 Planck discloses a composite multilayer implantable structure comprising two discrete layers: a first inner tubular layer 12' and a second outer tubular layer 12'' formed of ePTFE (3:15-25), said first 12' and second 12'' layers having a metallic support structure 11 (2:9-27) positioned there between and a third tubular layer 13 formed of a woven (3:19) textile material (4:46-54) disposed around the first 12' and second layers 12''. The support structure may be formed of monofilaments (3:1-7). The third textile layer 13 is adhered to the outer layer 12'' by adhesives (4:46-48). Planck discloses the claimed multilayer implantable prosthesis however fails to disclose the bonding agent, the application of the graft comprising a plurality of longitudinally spaced crimps, or that the bonding agent is applied in a solution of dimethylacetamide

Banas teaches a stent with ePTFE layers 36 surrounding a stent component 38 wherein the layers are bonded together by a silicon bonding agent (4:41-51) to form a vascular graft with an abluminal supporting structure capable of being diametrically reduced to an intraluminal delivery profile and self-expanding *in vivo* to conform to the anatomical topography at the site of intraluminal implantation (1:60+). The ePTFE graft maybe helically wrapped with the polypropylene (7:38-67) clad stent to form the tubular prosthesis (abstract). With reference to Figures 13 and 14 the elongate tubular graft of Banas comprises a plurality of longitudinally spaced crimps 88. Banas further discloses

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the method of heating the prosthesis to bond the layers together into a monolithic unitary structure (8:15-53). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the multilayer structure as disclosed by Planck in order to incorporate the method of applying the graft providing crimps as taught by Banas in order to produce a an implantable prosthesis that is capable of being reduced to a smaller size for delivery and self-expands upon implantation to conform to the patient's vasculature structure.

Planck as modified by Banas, as discussed above, discloses the implantable device as claimed. Planck as modified by Banas however fails to disclose that the bonding agent comprises a polycarbonate urethane and is applied in a solution of dimethylacetamide.

Pinchuk et al teaches coating stent grafts with a polycarbonate urethane bonding agent for the purpose of enhancing hoop strength and connectivity, and applying the bonding agent in the form of a solution comprising dimethylacetamide to accelerate the drying time or spray buildup for polyurethane. Therefore in view of the teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the implantable stent graft disclosed by Planck and modified by Banas by incorporating a polycarbonate urethane bonding solution of dimethylacetamide as taught by Pinchuk in order to speed up the polymerization of the polyurethane.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

CDP

CDP


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700